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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,013

12/23/2005

Francesco Makovec

Q91867

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23373 7590 08/03/2007
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EXAMINER

NAGUBANDI, LALITHA

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

08/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,013	Applicant(s) MAKOVEC ET AL.	
	Examiner Lalitha Nagubandi	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/23/2005</u> | 6) <input type="checkbox"/> Other: _____ |

Detailed Office Action

Status of the Claims

Claims 1-14 are pending in this application. Claims 1-14 are considered for examination in this office action.

Priority

This application is a 371 of PCT/IB04/02208 dated 06/21/2004, which claims benefit of Italy TO2003A000474, dated 06/21/2004.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makovec et al (US Pat. No. 5,130,474 dt. Jul. 14, 1992) and in view of Midler et al (US Pat No. 5,314,506 dt. May 24, 1994).

Applicants claim a method for the preparation of crystalline dexloxiglumide by crystallization of the crude product from solvent, characterized in that isopropyl ether is used as solvent. Applicants' have also embodied a method of crystallization step by adding a seeding of microcrystalline dexloxiglumide to a supersaturated solution of crude dexloxiglumide. Further, a pharmaceutical composition comprising dexloxiglumide is embodied in dependent claims.

Determination of Scope and content of the Prior Art (MPEP§2141.01)

Makovec et al teach (see Table 3, compound 11, US Pat. No. 5,130,474) preparation of crystalline dexloxiglumide and related compounds with antagonistic activity towards cholecystokin.

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Midler, Jr. et al teach (see col.1, lines 50 –60, US Pat. No. 5,314,506) a crystallization method to improve crystal structure and size with the help of seeding a supersaturated solution.

Ascertainment of the difference between the Prior Art and Claims (MPEP §2141.02)

The difference between the instant method and Makovec et al is that the instant process requires crystallization of the dexloxiglumide is carried out in presence of isopropyl ether. Makovec is silent about the use of isopropyl ether in the crystallization of dexloxiglumide. However, Makovec teaches the crystallization of the analogous products in presence of isopropyl ether. (see table 3, compounds 8 and 9, US Pat. No. 5,130,474).

Further, Makovec does not teach the crystallization step, by adding a seeding of microcrystalline dexloxiglumide to a supersaturated solution.

Midler teaches crystallization method with the help of seeding a supersaturated solution but does not teach explicitly the crystallization of dexloxiglumide.

Finding of prima facie obviousness – rational and motivation (MPEP § 2142-2143)

It would have been obvious to use isopropyl ether as the solvent to recover the dexloxiglumide during the crystallization process as disclosed by Makovec because a skilled artisan would be motivated to choose alternative solvents as a matter of choice depending on such factors as availability and cost.

It would have been obvious to one having ordinary skill in the art to have used the

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Crystallization technique as disclosed by Midler during the process of crystallization to improve crystal structure and size of dexloxiglumide with a reasonable expectation of success. Also a skilled artisan would purify the product obtained from the teaching of Makovec, as it is advantageous to use a pure product for further biological/clinical studies.

Accordingly, one of ordinary skill in the art would be motivated to prepare the instant products and compositions with anti-cholecystokinin activity with high purity by modifying the process parameters, using routine practices of crystallization.

Therefore the subject matter as a whole would have been obvious to one of ordinary skill in the art of process chemistry and one would have been motivated to combine and modify the teachings cited above at the time of the invention and obtain a reasonable expectation of success.

Conclusion

No claims are allowed

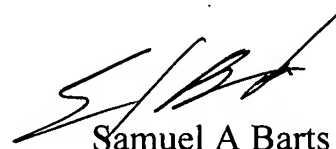
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalitha Nagubandi whose telephone number is 571 272 7996. The examiner can normally be reached on 6.30am to 3.30pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eyler, Yvonne can be reached on 571 272 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lalitha Nagubandi
Patent Examiner
Technology Center 1600

July 30th, 2007.



Samuel A Barts

Primary Patent Examiner
Technology Center 1600